

Exhibit 12

Note: Result is presented for the active ingredient, often including more than one brand name

Search

Ivermectin is an active ingredient

There are **6 303** reports with this active ingredient

Reported potential side effects

- › Blood and lymphatic system disorders (1%, 68 ADRs)
- › Cardiac disorders (2%, 158 ADRs)
- › Congenital, familial and genetic disorders (0%, 2 ADRs)
- › Ear and labyrinth disorders (1%, 63 ADRs)
- › Endocrine disorders (0%, 8 ADRs)
- › Eye disorders (3%, 277 ADRs)
- › Gastrointestinal disorders (18%, 1881 ADRs)
- ▼ General disorders and administration site conditions (18%, 1896 ADRs)
 - Drug ineffective (540)
 - Pyrexia (152)
 - Asthenia (145)
 - Fatigue (122)
 - Application site erythema (99)
 - Condition aggravated (99)
 - Malaise (93)
 - Pain (88)
 - Swelling face (83)
 - Application site pain (72)
 - Application site pruritus (70)
 - No adverse event (64)
 - Chest pain (50)
 - Gait disturbance (45)
 - Drug ineffective for unapproved indication (44)
 - Oedema (44)
 - Oedema peripheral (38)
 - Application site rash (36)
 - Face oedema (35)
 - Application site irritation (34)
 - Chills (34)
 - Swelling (34)
 - Death (25)
 - Drug effective for unapproved indication (23)
 - Therapeutic response unexpected (23)
 - Application site oedema (21)
 - Drug interaction (19)
 - Peripheral swelling (19)
 - Inflammation (16)
 - Feeling abnormal (15)
 - Therapeutic response decreased (14)
 - Adverse event (13)
 - Application site swelling (13)
 - Generalised oedema (13)
 - Discomfort (11)
 - Feeling hot (11)
 - Feeling cold (10)
 - Multiple organ dysfunction syndrome (10)
 - Therapy non-responder (9)
 - Treatment failure (9)
 - Unevaluable event (9)
 - Application site inflammation (8)
 - Chest discomfort (8)
 - Application site discharge (7)
 - Localised oedema (7)

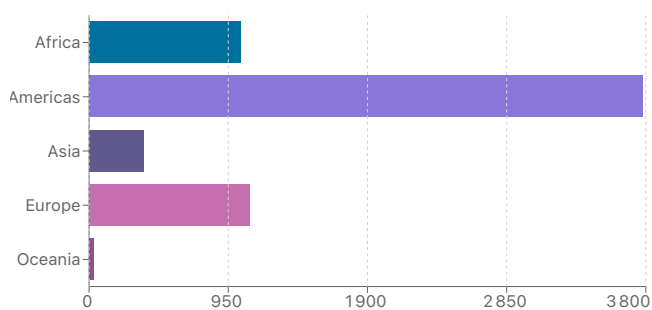
Application site dryness (3)
Disease recurrence (5)
General physical health deterioration (5)
Tenderness (5)
Therapeutic product effect incomplete (5)
Treatment noncompliance (5)
Application site vesicles (4)
Feeling drunk (4)
Adverse reaction (3)
Application site acne (3)
Application site burn (3)
Application site discolouration (3)
Application site exfoliation (3)
Application site papules (3)
Application site reaction (3)
Crying (3)
Ill-defined disorder (3)
Influenza like illness (3)
Injury associated with device (3)
Mucosal dryness (3)
Secretion discharge (3)
Sudden death (3)
Therapeutic product effective for unapproved indication (3)
Adverse drug reaction (2)
Application site haemorrhage (2)
Application site hypersensitivity (2)
Application site warmth (2)
Cyst (2)
Disease progression (2)
Drug intolerance (2)
Facial pain (2)
Hyperpyrexia (2)
Illness (2)
Injection site pain (2)
Physical deconditioning (2)
Rebound effect (2)
Systemic inflammatory response syndrome (2)
Ulcer (2)
Administration site erythema (1)
Administration site pain (1)
Administration site reaction (1)
Administration site swelling (1)
Adverse food reaction (1)
Application site dermatitis (1)
Application site discomfort (1)
Application site nodule (1)
Application site photosensitivity reaction (1)
Application site plaque (1)
Application site scab (1)
Application site urticaria (1)
Application site wound (1)
Axillary pain (1)
Chronic fatigue syndrome (1)
Complication associated with device (1)
Crepitations (1)
Early satiety (1)
Energy increased (1)
Extensive swelling of vaccinated limb (1)
Hangover (1)
Hyperthermia (1)
Hypothermia (1)
Impaired self-care (1)
Injection site haemorrhage (1)
Local reaction (1)
Mass (1)
Mucosal inflammation (1)
Nodule (1)
Nonspecific reaction (1)
Paradoxical drug reaction (1)
Performance status decreased (1)
Sluggishness (1)
Temperature intolerance (1)
Therapeutic product effect delayed (1)
Therapeutic product ineffective (1)

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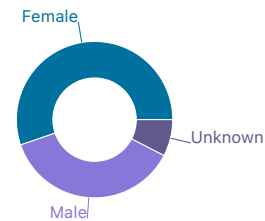


- Therapeutic response delayed (1)
- Thirst (1)
- > Hepatobiliary disorders (1%, 101 ADRs)
- > Immune system disorders (1%, 81 ADRs)
- > Infections and infestations (2%, 259 ADRs)
- > Injury, poisoning and procedural complications (8%, 870 ADRs)
- > Investigations (1%, 140 ADRs)
- > Metabolism and nutrition disorders (2%, 183 ADRs)
- > Musculoskeletal and connective tissue disorders (3%, 294 ADRs)
- > Neoplasms benign, malignant and unspecified (incl cysts and polyps) (0%, 11 ADRs)
- > Nervous system disorders (13%, 1340 ADRs)
- > Pregnancy, puerperium and perinatal conditions (0%, 10 ADRs)
- > Product issues (1%, 56 ADRs)
- > Psychiatric disorders (2%, 252 ADRs)
- > Renal and urinary disorders (1%, 154 ADRs)
- > Reproductive system and breast disorders (0%, 43 ADRs)
- > Respiratory, thoracic and mediastinal disorders (2%, 239 ADRs)
- > Skin and subcutaneous tissue disorders (18%, 1929 ADRs)
- > Social circumstances (0%, 14 ADRs)
- > Surgical and medical procedures (0%, 31 ADRs)
- > Vascular disorders (1%, 137 ADRs)

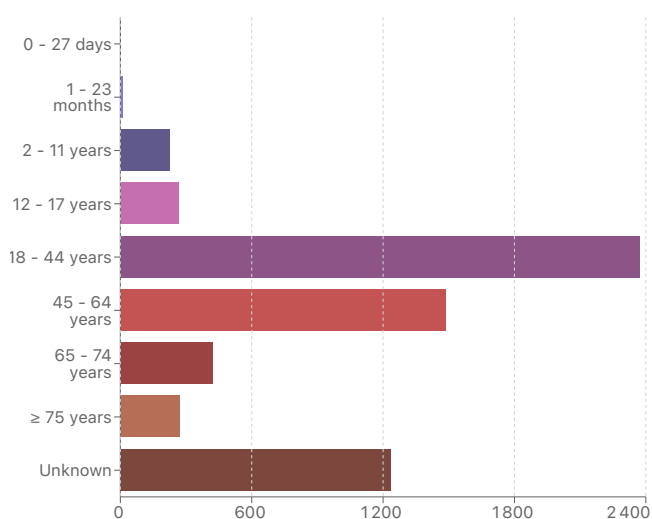
Geographical distribution

[Chart](#) [Table](#)

Patient sex distribution

[Chart](#) [Table](#)

Age group distribution

[Chart](#) [Table](#)

ADR reports per year

[Chart](#) [Table](#)

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Current data set date is 5/8/2022. The dataset is normally updated on Sundays at 17:00 CET (± 1 hour).



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